

1 (II) REMARKS:  
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3 Detailed discussion and comparison of prior arts and the present patent in responding the  
4 comments from the Examiner are shown a follows:  
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- 6 (1) "system" is changed to "method" in all Claims such that they will be consistent with the main  
7 Claim #1 which is a "method".  
8 (2) Claims 21 and 22 which are indefinite and were deleted.  
9  
10 (3) Relating to Claims 1,8,16-20 of the present patent, there are several fundamental  
11 differences between the prior art of O'Donnell (6,197,018, "Pat-018") and the present patent:  
12  
13 a) Pat-018 used "thermal" lasers to cause shrinkage of the corneal "lens" portion, whereas  
14 the present patent required "cold" lasers to ablate the sclera tissue outside the limbus.  
15 b) the diode lasers of (0.95-2.1) proposed by the present patent to ablate tissue requires the  
16 laser power density to be big enough (above the ablation threshold) to avoid thermal  
17 effects. Whereas Pat-018 require a low power just to keep the thermal effects without  
18 remove tissues or the lens. Pat-018 also proposed IR laser of (0.8 - 1.9) um but required  
19 at low power. If one applies these low power lasers to the sclera tissue, the end results  
20 will be the thermal damage of the cornea rather than excision (ablation).  
21 c) Mechanism of Pat-018 is to "directly" shrink the lens structure and cause its shape to  
22 change for presbyopia patient's accommodation. Whereas the mechanism proposed by  
23 the present patent is to increase the "flexibility" of the sclera tissue such that patient can  
24 accommodate his near view by contract the lens via the zonulus fiber. These two  
25 mechanisms are totally different.  
26 d) Pat-018 has never been clinically tested and it would be very hard to define a laser to  
27 penetrate the cornea without absorption and only selectively heating the lens area.  
28 The method proposed by the present patent using cold lasers has been clinically proven  
29 for efficacy and clinical data was reported by the inventor during 1999-2001 in many  
30 conference. In addition, Pat-018 will be a high risk method with potential of causing  
31 cataracts, if the laser is not precisely target at the lens boundary.  
32  
33 (4) The laser-tissue interaction area cited in prior arts patented by Mathis (5,599,341), Sawusch  
34 (6,171,336), Balgorod (5,102,409) and Payman (6,203,538) are also fundamental different  
35 from the method proposed by the present patent:  
36  
37 (a) all above prior arts are using lasers to interact within the central portion of the cornea,  
38 whereas the laser ablation proposed by the present patent is outside the corneal limbus area.  
39 (b) In all the above prior arts, the laser was used to change corneal curvature by ablation the  
40 corneal surface or its stroma or thermally shrink the corneal shape such that patients' vision is  
41 corrected. And these corrections are ONLY good for myopia and hyperopia and CAN NOT  
42 correct presbyopia. The presbyopia correction proposed in the present patent, on the contrary,  
43 does not change the corneal central curvature but only increase the accommodation of the lens by  
44 removing portion of the sclera tissue outside the limbus.  
45 (c) Presbyopia correction by a laser is a new procedure which is TOTALLY different from the  
46 teaching of prior arts using lasers for corneal "reshaping". Presbyopia correction also requires  
47 patient's far view unchanged (or without reshaping of the cornea) and only improve the near-view  
48 by lens accommodation.  
49 (d) Furthermore, the present patent uses a "cold" laser to remove sclera tissue (outside the  
50 limbus area) versus a "thermal" lasers in Sand's patent (Pat. No. 5,484,432) to shrink the corneal  
51 shape (inside the limbus area).  
52 (e) Prior art of Sawusch also proposed a thermal laser to shrink the implants. He also  
53 proposed the incision by surgical blade which will cause regression after the tissue healing (close  
54 up). Whereas the laser ablation proposed by the present patent cause no regression because the  
55 laser removed sclera tissue which is filled in by the sub-conjunctiva tissue and remains the

1 effects. Surgical blades did not remove tissue and only incises tissue.

2  
3 (5) prior arts of Hammer (5,738,676) used fiber to remove membrane within the eye cavity,  
4 which is not suitable for the procedure proposed by the present patent. The teaching of Neev  
5 (6,156,030) and Rizoio (5,741,247) to reduce the thermal effect of laser-matter interaction is  
6 not require in the present patent. The prior art of Tsushima using a special wedge-like fiber to  
7 optimize the coupling efficiency is not required in the present patent. The fiber shapes  
8 proposed in the present patent is to use various laser beam spot shapes and size such that  
9 sclera tissue may be easily remove in a controlled manner (with depth and patterns), which  
10 do not require any of the teaching from the prior arts.

11  
12 In view of the above discussion, the present inventor believes that it would be non-obvious to a  
13 normal skill person to utilize the teachings provided by the prior arts of O'Donnell, Mathis, Rozoiu  
14 etc to achieve the "presbyopia" correction (defined by patient's accommodation) proposed in the  
15 present patent. In fact, the concept of laser scleral ablation outside the limbus area (rather than  
16 reshaping the central portion of the cornea) is innovative and has been clinically tested based the  
17 proposed techniques in the present patent. The present inventor has used these technique to  
18 treat over 150 cases of presbyopia patients with very good results and almost no regression after  
19 longer than 24 months follow up. These clinical results based on the teaching proposed in the  
20 present patent have not been explored by any of the prior arts, except those pending patents of  
21 the present inventor.

22  
23  
24 (III) Version with marking to show changes made in Claims:

25  
26 1. A System (changed to A Method), adaptable for performing presbyopic correction in which a  
27 portion of the corneal sclera tissue is removed by steps of :

- 28  
29 (a) selecting a laser beam having a predetermined wavelength ;  
(b) selecting a beam spot controller mechanism, said beam spot controller to reduce and  
focus said laser beam to a fiber delivery unit;  
(c) controlling the said fiber delivery unit to deliver said laser beam in a said  
predetermined pattern onto a plurality of positions on the corneal surface to remove  
portion of the sclera tissue outside the limbus area, whereby a presbyopic patient's  
vision is corrected to see near (deleted) and far by increasing the accommodation of  
the (add) corneal lens.

2. A method of claim 1, wherein said laser beam is an ultraviolet laser having a wavelength  
range of about (0.15 - 0.36) microns and a pulse duration less than about 200 nanoseconds.

3. A method of claim 1, wherein said laser beam is an infrared laser having a wavelength  
range of about (1.4 - 3.2) microns.

4. A method of claim 2 (changed to 3), wherein infrared laser is an optically pumped  
Erbium:YAG laser having a wavelength of about 2.9 microns.

5. A method of claim 1, wherein said laser beam is an ArF excimer laser having a wavelength  
of 193 nm.

6. A method of claim 1, wherein said laser beam is a XeCl excimer laser having a wavelength  
of 308 nm.

7. A method of claim 1, wherein said laser beam is a solid state diode laser having a  
wavelength range of about (0.95 – 2.1) microns (add) with a power higher than 2 Watt and  
focused to a spot size less than 0.5 mm on the cornea surface.

8. A method of claim 1, in which said beam spot controller consists of at least one focusing spherical lens to couple the said laser beam to the said fiber delivery unit.
9. A method of claim 1, wherein said fiber delivery unit consists of an optical fiber having a length of about (0.5 - 1.5) meter and core diameter of about (0.2 - 0.8) mm and a hand piece connected to a fiber tip.
10. A method of claim 9, wherein said fiber delivery unit is substantially transparent to the wavelength of the said laser beam.
11. A method of claim 9, wherein said fiber tip is made of a similar material as that of the fiber and is made in one of the following shapes to focus the said laser beam onto the treated sclera area of the eye: conical, spherical, 90-degree reflecting angle and flat end.
12. A method of claim 9, wherein said fiber tip focuses the said laser beam onto the treated area of the eye at a spot size of about (0.1 - 0.5) mm in diameter.
13. A method of claim 9, wherein said fiber tip is made in a cylinder shape to focus the said laser beam onto the treated area of the eye at a line shape having a dimension of about (0.1 - 0.4) in width and (0.5 - 4.0) mm in length.
14. A method of claim 9, wherein said fiber tip is operated in a contact-mode to ablate the sclera tissue to a depth of about (300 - 800) microns.
15. A method of claim 9, wherein said fiber tip is operated in a non-contact mode to ablate the sclera tissue to a depth of about (300 - 800) microns.
16. A method of claim 1, wherein said fiber delivery unit is controlled by the surgeon to perform a predetermined patterns outside the limbus of the cornea by manually moving the fiber tip in the radial direction of the cornea.
17. A method of claim 1, wherein said fiber delivery unit is attached to a scanning device to perform said predetermined patterns outside the limbus of the cornea and scan said laser beam along the radial direction of the cornea.
18. A method of claim 1, wherein said predetermined patterns outside the limbus of the cornea defined by the area between two circles having radius of about 5.0 mm and 9.0 mm, respectively.
19. A method of claim 1, wherein said predetermined pattern includes at least 3 radial lines around the area outside the corneal limbus.
20. A method of claim 1, wherein said predetermined pattern includes at least two rings formed by 8 circular spots having a diameter of about (0.2 - 0.5) mm around the area outside the corneal limbus.
21. (deleted this Claim) A method of claim 1, wherein said sclera tissue is removed by said laser beam after the cornea conjunctiva is open.
22. (deleted this Claim) A method of claim 1, wherein said sclera tissue is removed by said laser beam without opening the cornea conjunctiva.